K013557

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BIOMET

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Walter Lorenz Surgical, Inc.
(A wholly owned subsidiary of Biomet, Inc.)
1520 Tradeport Drive
P.O. Box 18009
Jacksonville, Florida 32229-8009

Contact Person: Tracy J. Bickel
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587
(219) 267-6639

Proprietary Name: LactoSorb® Craniofacial Anchor-Push Screw

Common or Usual Name: Resorbable soft tissue device

Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue (MBI)

Substantially Equivalent Devices: Craniofacial Anchors (K974136)

Device Description: The Craniofacial Anchor-Push Screw is a resorbable (LactoSorb®) screw. The device is a screw that is directly inserted into a pre-drilled hole. The Push Screws utilize the same auxiliary break-off hex head as the cleared LactoSorb® Craniofacial Anchors.

Intended Use: The Craniofacial Anchor-Push Screw's are indicated for use to assist resorbable suture in open and endoscopic brow lift procedures.

Summary of Technologies: Minor changes were made to the drive mechanism of the screw. In terms of overall design, material, function, as well as intended use, the LactoSorb® Craniofacial Anchor-Push Screw is equivalent to the predicate device.

Non-Clinical Testing: Mechanical testing was completed to determine substantial equivalence.

Clinical Testing: Clinical testing was not used to determine substantial equivalence.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE: 219.267.6639 ■ FAX: 219.267.8137 ■ E-MAIL: biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2001

Walter Lorenz Surgical, Incorporated
C/O Ms. Tracey J. Bickel
Biomet Orthopedics, Incorporated
P. O. Box 587
Warsaw, Indiana 46581-0578

Re: K013557
Trade/Device Name: Lactosorb Cranifacial Anchor-Push Screw
Regulation Number: 888.3030 and 872.4880
Regulation Name: Resorbable Soft Tissue Device
Regulatory Class: II
Product Code: HWC and DZL
Dated: October 23, 2001
Received: October 24, 2001

Dear Ms. Bickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 6 2001

510(k) Number (if known): K013557
Device Name: **LactoSorb® Craniofacial Anchor-Push Screw**
Indications for Use:

The Craniofacial Anchor-Push Screw's are indicated for use to assist resorbable suture in open and endoscopic brow lift procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013557